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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/533,381	03/22/2000	Nicola Fanto	2801-14	8341
23117	7590	08/24/2004	EXAMINER BARTS, SAMUEL A	
NIXON & VANDERHYE, PC 1100 N GLEBE ROAD 8TH FLOOR ARLINGTON, VA 22201-4714			ART UNIT 1621	PAPER NUMBER

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/533,381

Applicant(s)

FANTO ET AL.

Examiner

Samuel A Barts

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1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's amendment to the claims filed March 26, 2003 has obviated some of the species in the prior art of Weinstock et al. Applicant has failed to correctly amend the claims to exclude all the compounds taught in Weinstock et al. Furthermore, applicant has failed to overcome the rejection of claim 10 presented in the previous office action. Please note that claim 10 is rejected over the compound 2-amino-6-fluoro-7-hydroxytetraline hydrochloride not 2-amino-6-chloro-7-hydroxytetraline hydrochloride as alleged in applicant's response.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8, 9, and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are rejected as prolix since the numerous provisos have rendered the metes and bounds of the claimed subject matter indefinite. The claims are now more drawn to what they exclude than what they include. MPEP 2170.05(m)

Claim Rejections - 35 USC § 102

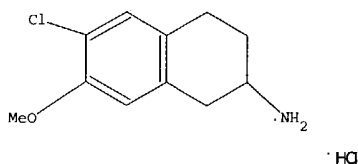
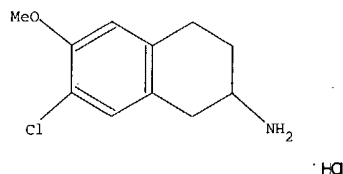
2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 8, 9, and 11 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Weinstock et al (J.Med Chem. 1986, vol 29, pages 1615-1627).

Weinstock et al teach the following compounds:



The instant claims read on the compounds taught in Weinstock et al when R=halogen (Cl), R₁=OCH₃, and R₂= hydrogen and when R=OCH₃, R₁= halogen (Cl), and R₂= hydrogen.

Claim 11 is also anticipated because the above compounds were all made in the prior art of Weinstock et al and the final compositions read inherently on an "orally or parenterally administrable pharmaceutical composition".

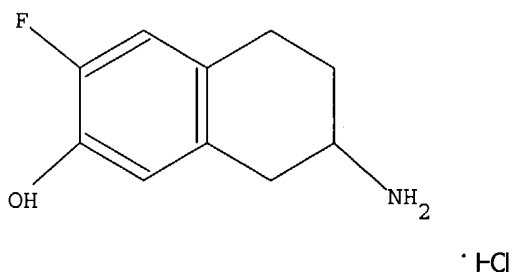
Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weinstock et al (J.Med Chem. 1986, vol 29, pages 1615-1627).

Weinstock et al teach the compound 2-amino-6-fluoro-7-hydroxytetraline hydrochloride.



Weinstock et al is silent about the optical isomers. However, the structure has a chiral center and therefore, will inherently have the optical isomers in equal amounts (i.e. the compound is a racemate). The compositions made in

Weinstock et al are racemic mixtures of the first two claimed compounds of claim 10. The compounds are useful as dopaminergic agents.

The difference between the claimed invention and the prior art is that claimed invention is directed to the optical isomers of 2-amino-6-fluoro-7-hydroxytetraline hydrochloride. This difference is not patentable.

It would have been obvious to one having ordinary skill in the art at the time that applicant's invention was made to have isolated the optical isomers of 2-amino-6-fluoro-7-hydroxytetraline hydrochloride with a reasonable expectation that one of the isomers would have the dominant pharmacological activity. One skilled in the art would be motivated to isolate the optical isomers in order to make more potent dopaminergic active compositions. Additional motivation lies in the fact, that there is a reasonable expectation that the side effects usually associated with the racemic mixture can be eliminated if they are the result of the optical isomer that is not responsible for the desired pharmacological activity.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel A Barts whose telephone number is 571-272-2870. The examiner can normally be reached on 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johan Richter can be reached on 308-1235. The fax

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phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A handwritten signature in black ink, appearing to read 'S. A. Barts', with a stylized flourish at the end.

Samuel A Barts
Primary Examiner
Art Unit 1621

s.b.
June 13, 2003